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**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA**

IN RE: VIAGRA (SILDENAFIL CITRATE)  
AND CIALIS (TADALAFIL) PRODUCTS  
LIABILITY LITIGATION

Case No. 3:16-md-02691-RS

MDL No. 2691

This Document Relates to:  
  
ALL ACTIONS

**DECLARATION OF LOREN H. BROWN  
IN SUPPORT OF DEFENDANTS PFIZER  
AND LILLY'S MOTION TO EXCLUDE  
PLAINTIFFS' EXPERTS' OPINIONS**

I, Loren H. Brown, make this declaration under penalty of perjury in support of Defendants Pfizer Inc. and Eli Lilly and Company's Motion to Exclude Plaintiffs' Experts' Opinions and submit the following information:

1. I am an attorney at the law firm DLA Piper LLP (US), counsel of record for Defendant Pfizer Inc. in the above-titled action. I am licensed to practice law in the state of New York and admitted *pro hac vice* in this matter. I make this declaration based on my own personal knowledge and, if called as a witness, could and would testify competently to the matters set forth below.

2. I certify that the exhibits included in the attachment hereto are true and correct copies, submitted on behalf of Defendants Pfizer Inc. and Eli Lilly and Company in support of their Motion to Exclude Certain Plaintiffs' Experts' Opinions. True and correct copies of the exhibits listed on the attached are electronically filed with this Court using the CM/ECF system.

Dated: January 11, 2019

Respectfully submitted,

DLA PIPER LLP (US)

BY: /s/ Loren H. Brown

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**ATTACHMENT**

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## Exhibit List to Defendants Pfizer and Lilly's Motion to Exclude Plaintiffs' Experts' Opinions

| Daubert<br>Defense<br>Ex. # | Description   | Date       | Orig. Ex. #<br>(If Joint Exhibit has been<br>used as Deposition Exhibit)<br>(if any) |
|-----------------------------|---|------------|--|
| 1                           | Viagra Label  | 12/14/2017 |  |
| 2                           | Cialis Label  | 2/15/2018  |  |
| 3                           | Burnett et al., AUA Educ. & Research, Inc., Erectile Dysfunction: AUA Guideline, Apr. 2018:1-70.  | 04/2018    |  |
| 4                           | Center for Drug Evaluation and Research, VIAGRA Drug Approval Package (Sections 1-10) (Excerpted)   | 3/27/1998  |  |
| 5                           | Pfizer Response to PRAC Request for Supplementary Information, August 29, 2014  | 8/29/2014  | Witte, Ex. 5   |
| 6                           | Sildenafil Toxicology-Pharmacological Expert Report, Appendix 4 (Excerpted)   | 1/21/2004  |  |
| 7                           | Goldstein et al., The Serendipitous Story of Sildenafil: An Unexpected Oral Therapy for Erectile Dysfunction, Sex Med Rev. 2018;1-14.   | 10/6/2018  |  |
| 8                           | FDA Approval Letter for Viagra  | 3/27/1998  |  |
| 9                           | FDA Approval Letter for Cialis  | 11/21/2003 |  |
| 10                          | FDA Supplemental Approval Letter for Cialis   | 1/7/2008   |  |
| 11                          | FDA Supplemental Approval Letter for Cialis   | 10/6/2011  |  |
| 12                          | Lilly Safety Topic Report: Prostate, Bladder, and Skin Cancer   | 12/2/2014  |  |
| 13                          | Lilly Safety Topic Report: Melanoma   | 12/2/2016  |  |
| 14                          | FDA Approval Letter for Revatio   | 6/3/2005   |  |
| 15                          | Revatio Label   | 2/1/2018   |  |
| 16                          | FDA Approval Letter for Adcirca   | 5/22/2009  |  |
| 17                          | Adcirca Label   | 5/5/2017   |  |
| 18                          | US Patent No. 5,858,694 titled Method for Identifying Compounds for Inhibition of Cancerous Lesions   | 1/12/1999  | Piazza Ex. 34  |
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| 21                          | Confino et al., Inhibition of mouse breast adenocarcinoma growth by ablation with intratumoral alpha-irradiation combined with inhibitors of immunosuppression and CpG, Cancer Immunol Immunother. 2016;65(10):1149-58. | 10/2016    |  |
| 22                          | Tavallai et al., Nexavar/Stivarga and Viagra interact to kill tumor cells, J Cell Physiol. 2015;230(9):2281-98.   | 9/2015     |  |
| 23                          | Black et al., PDE5 inhibitors enhance tumor permeability and efficacy of chemotherapy in a rat brain tumor model, Brain Res. 2008;1230:290-302.   | 9/16/2008  |  |
| 24                          | Sharman et al., Cyclic-GMP-Elevating Agents Suppress Polyposis in ApcMin mice by Targeting the Preneoplastic Epithelium, Cancer Prev Res. 2018;11(2):81-92.   | 2/2018     |  |
| 25                          | Qian et al., Effect of sildenafil citrate on an orthotopic prostate cancer growth and metastasis model, J Urol. 2003;170:994-97.  | 9/2003     |  |
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| 27                          | Serafini et al., Myeloid-derived suppressor cells promote cross-tolerance in B-cell lymphoma by expanding regulatory T cells, Cancer Res. 2008;68(13):5439-49.  | 7/1/2008   |  |
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| 29                          | Islam et al., Sildenafil Suppresses Inflammation-Driven Colorectal Cancer in Mice, Cancer Prev Res. 2017;10(7):377-388.   | 7/2017     | Piazza Ex. 29  |
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|-----------------------------|---|------------|--|
| 32                          | Das et al., Sildenafil increases chemotherapeutic efficacy of doxorubicin in prostate cancer and ameliorates cardiac dysfunction, Proc Natl Acad Sci USA. 2010;107(42):18202-07.                                  | 10/19/2010 |  |
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| 35                          | Charles Toutant, <i>Lawyers Ready Suits Claiming Viagra Caused Skin Cancer</i> , N.J. L.J. (LAW.com.)   | 11/13/2014 |  |
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| 42                          | Pfizer Response to June 03, 2016 FDA Information Request  | 7/15/2016  |  |
| 43                          | Preliminary PRAC Rapporteur Assessment Report on the Signal of Melanoma with Sildenafil   | 10/13/2014 |  |
| 44                          | European Medicines Agency PRAC PSUR Assessment Report Tadalafil   | 6/11/2015  |  |
| 45                          | European Medicines Agency PRAC PSUR Assessment Report Tadalafil   | 6/9/2017   |  |
| 46                          | FDA Division of Epidemiology (DEPI), Review of Published Study Report (FDA00000024)   | 3/4/2015   |  |
| 47                          | FDA Division of Epidemiology (DEPI), Literature Review on the Association Between [PDE5] Inhibitors and Risk of Malignant Melanoma (FDA00000040)  | 4/27/2016  |  |
| 48                          | FDA Division of Pharmacovigilance II, Melanoma and PDE5 Inhibitors (FDA00000001)  | 8/19/2016  | Ballman Ex. 25   |
| 49                          | American Academy of Dermatology, Practice Management Center, <u>Erectile dysfunction drugs and skin cancer</u> .  | 4/16/2018  | Ahmed Ex. 6  |
| 50                          | Weed et al., Tadalafil Reduces Myeloid-Derived Suppressor Cells and Regulatory T Cells and Promotes Tumor Immunity in Patients with Head and Neck Squamous Cell Carcinoma, Clinical Cancer Res. 2015;21(1):39-48. | 1/1/2015   | Califano Ex. 22  |
| 51                          | Califano et al., Tadalafil Augments Tumor Specific Immunity in Patients with Head and Neck Squamous Cell Carcinoma, Clin Cancer Res. 2015;21(1):30-38.  | 1/6/2015   | Califano Ex. 7; Ballman Ex. 23   |
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| 53                          | Initial Expert Report of Dr. Singh ( <i>In re: Lipitor (Atorvastatin Calcium) Marketing, Sales Practices and Products Liability Litigation</i> , MDL No. 2:14-mn-02502) (Redactions In Original As-Filed Version) | 3/4/2015   |  |
| 54                          | Supplemental Expert Report of Dr. Singh ( <i>In re: Lipitor (Atorvastatin Calcium) Marketing, Sales Practices and Products Liability Litigation</i> , MDL No. 2:14-mn-02502) (Filed Under Seal)                   | 12/7/2015  |  |
| 55                          | Turner et al., Thiazolidinediones and associated risk of bladder cancer: a systematic review and meta-analysis, Br J Clin Pharmacol 2013;78:2   |            |  |
| 56                          | Deposition Transcript of Dr. Singh, Vol. 1 and Vol. 2 (Excerpted) ( <i>In re: Lipitor (Atorvastatin Calcium) Marketing, Sales Practices and Products Liability Litigation</i> , MDL No. 2:14-mn-02502)            | 4/28/2015  |  |
| 57                          | Dr. Singh Expert Report in <i>Lauris v. Novartis AG</i> , No. 1:16-cv-00393-SHE (E.D. Cal.), Dkt. No. 112-1   | 6/1/2017   |  |
| 58                          | Dr. Singh Expert Report in <i>McWilliams v. Novartis AG</i> , No. 2:17-cv-14302 (S.D. Fla.), Dkt. No. 56-3  | 2/20/2018  |  |
| 59                          | Garrett, et al., Incidence of and Risk Factors for Skin Cancer in Organ Transplant Recipients in the United States, JAMA Dermatol. 2017;153(3):296-303.   | 3/1/2017   |  |

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|-----------------------------|--|--|--|
| 60                          | Whitt, et al. (Piazza), Sulindac sulfide selectively increases sensitivity of ABCC1 expressing tumor cells to doxorubicin and glutathione depletion, J Biomed Res. 2016;30(2):120-133.   | 3/2016                                 | Piazza Ex. 18, 40  |
| 61                          | Piazza, Validation of PDE5 as a Chemoprevention Target, Cancer Prev Res. 2017;10(7):373-376.   | 7/2017                                 | Piazza Ex. 19  |
| 62                          | U.S. Patent Application No. US 20160143912 A1 and U.S. Patent No. 10,039,764 B2 titled Treatment and Diagnosis of Cancer and Precancerous Conditions Using PDE10A Inhibitors and Methods to Measure PDE10A Expression                | 6/18/2018<br>(application)<br>8/7/2018 | Piazza Ex. 27  |
| 63                          | US Patent No. 9,365,528 B2 titled Derivatives of Sulindac, Use Thereof and Preparation Thereof   | 6/14/2016                              | Piazza Ex. 28  |
| 64                          | El-Sharkawy et al., Design and synthesis of novel annulated thienopyrimidines as phosphodiesterase 5 (PDE5) inhibitors, Arch Pharm. 2018;351(5):e1800018.  | 5/2018                                 | Piazza Ex. 33  |
| 65                          | US Patent No. 6,156,528 titled Methods for Using a Phosphodiesterase in Pharmaceutical Screening to Identify Compounds for Treatment of Neoplasia  | 12/5/2000                              | Piazza Ex. 35  |
| 66                          | Tinsley, et al., Inhibition of PDE5 by sulindac sulfide selectively induces apoptosis and attenuates oncogenic Wnt/ $\beta$ -catenin-mediated transcription in human breast tumor cells., Cancer Prev Res (Phila) 2011;4(8):1275-84. | 8/2011                                 | Piazza Ex. 36  |
| 67                          | US Patent No. 9,388,139 B2 titled Derivatives of Celecoxib, Use Thereof and Preparation Thereof  | 7/12/2016                              | Piazza Ex. 37  |
| 68                          | Ahmed, et al. (Piazza), Exploring the PDE5 H-pocket by ensemble docking and structure-based design and synthesis of novel $\beta$ -carboline derivatives, Eur J Med Chem. 2012;57:329-43.  | 9/24/2012                              | Piazza Ex. 38  |
| 69                          | Gurpinar et al. (Piazza), COX-independent mechanisms of cancer chemoprevention by anti-inflammatory drugs, Front Oncol. 2013; 3;181.   | 7/11/2013                              | Piazza Ex. 39  |
| 70                          | National Cancer Institute, Division of Cancer Predention, Grant R01CA155638, <i>Phosphodiesterase 5: A Novel Target and Inhibitor for Breast Cancer Chemoprevention</i> , Gary A. Piazza, University of South Alabama                | 7/6/2018                               | Piazza Ex. 43  |
| 71                          | Letter from Christine P. Nguyen, FDA Office of Drug Evaluation III, to Pfizer Inc.   | 6/3/2016                               |  |

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was electronically filed through the Court's CM/ECF system on January 11, 2019, which shall send notification of such filing to all CM/ECF participants.

/s/ Loren H. Brown  
Loren H. Brown